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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,468	07/10/2003	Patrick M. Hughes	17549 (AP)	3251

7590
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07/06/2007

EXAMINER

BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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07/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/617,468	Applicant(s) HUGHES ET AL.	
	Examiner Timothy E. Betton	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4 sheets</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse in the reply filed on 15 June 2007 is acknowledged. The traversal is on the ground(s) that since all claims of both Groups I and II are limited to an ester prodrug of an active drug, [thus] a single search should suffice to search all claims.

Applicants' traverse is not found persuasive. Instant Claims 1-17 and 19 (Group I) are drawn toward a method of sustained delivery of an active drug to the posterior part of an eye of a mammal.

Group II (Claim 18 and 20) are drawn to a practicing pharmaceutical product comprising a composition containing an effective concentration of an ester prodrug of an active drug, which further discloses a suitable packaging material, which comprises instructions. Group II contains embodiments of a separate invention. Group I and Group II are mutually exclusive in that the suitable packaging material as instant claim 18 discloses could be used for a materially different drug agent than the one disclosed in instant invention.

Information Disclosure Statement

Applicants' reference (CM) cited on page 2 of 3 is lined out because it lacks the required date of publication.

Please correct.

Election/Restriction

Applicants' election of Group I, which is drawn to Applicants, elect Group I, claims 1-17 and 19 with traverse on the basis that since all claims of both Groups I and II are limited to a an ester prodrug of an active drug, therefore a single search should suffice to search all the claims.

Additionally, and as also requested by the Office Action, applicant elects the drug retinoids. The claims which appear to be readable on this elected polymer are claims 1-17 and 19.

Additionally, and as also requested by the Office Action, applicant elects the disease proliferative vitreal retinopathy. The claims, which appear to be readable on this elected polymer, are claims 1-17 and 19. As further requested by the office action, applicant elects as the route of administration subconjunctival. The claims, which appear to be readable on this elected drug species, are claims 1-17 and 19.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejection-35USC 112, 1ST paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17, and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a disease or condition directed toward

the posterior of the eye, does not reasonably provide enablement for prevention of a disease or condition as disclosed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants' disclosure directed toward prevention is not described in the invention. There is data, which clearly suggests treatment or palliation of such ocular conditions in the instant specification. However, applicants' alleged scope of enablement directed to a preventive practice is not properly elucidated in the instant claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Exparte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The Board also stated that although the level of skill in the pertinent art is high, the results of experimentation in treating a person seeking rapid relief/prevention of ill-effects of ingesting alcohol. While all these factors are considered, a sufficient amount for a prima facie case are discussed below:

The nature of the invention

This invention is drawn to methods of delivering a drug. More particularly, the present invention relates to methods of delivering an active drug to a posterior part of the eye of a mammal.

The amount of direction or guidance provided

There is an insufficient amount of direction or guidance provided due to scope of invention drawn to prevention.

Vitreous retinopathy is a condition, which is common to diabetics. For exemplary purposes, prevention in the case of a condition such as vitreous retinopathy is tentatively possible through effective control of blood sugar levels, insulin therapy (Type I), medication (Type II) and dietary measures delays the onset and slows the progression of retinopathy. Laser therapy, set aside from the claims of instant invention has been proven to be the most effective than any other therapy at palliating vitreous retinopathy. However, the most effective therapies for vitreous retinopathy are only effective in part. Thus, the therapies as disclosed above as a formulative regimen have been proven in the art as the most effective way in the realm of prevention of such disease states

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(VisionRX, Encyclopedia-Diabetic Retinopathy (2007), printed pages 1-4, especially pages 1-3)(Penn State Milton S. Hershey Medical Center College of Medicine, Health and Disease Information, A to Z Topics, Diabetic Retinopathy, (2007), printed pages 1-5).

The quantity of experimentation necessary

The quantity of experimentation is high. One of ordinary skill in the pertinent would instantly recognize the necessity for due experimentation. In the case of instant specification, applicants have disclosed embodiments within the specification drawn to treatment. However, there are no embodiments within instant specification, which suggest instant invention preventing the disease classifications and conditions disclosed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

 7/1/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER